

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**Before the Board of Patent Appeals and Interferences**

Applicant: Klaus Abraham-Fuchs

Serial No.: 09/742,268

Filed: December 20, 2000

For: METHOD AND SYSTEM FOR ALLOWING A NEUROLOGICALLY  
DISEASED PATIENT TO SELF-MONITOR THE PATIENT'S ACTUAL  
STATE

Examiner: Vanel Frenel

Art Unit: 3627

**APPEAL BRIEF**

May It Please The Honorable Board:

Appellants appeal the Rejection, dated January 3, 2007 of Claims 1-28 of the above-identified application. The fee of five hundred dollars (\$500.00) for filing this Brief and any associated extension fee is to be charged to Deposit Account No. 19-2179. Enclosed is a single copy of this Brief.

Please charge any additional fee or credit any overpayment to the above-identified Deposit Account.

Appellants do not request an oral hearing.

**I. REAL PARTY IN INTEREST**

The real party in interest of Application Serial No. 09/742,268 is the Assignee of record:

Siemens Medical Solutions Health Services Corporation  
51 Valley Stream Parkway  
Malvern, PA 19355-1406

which merged into Siemens Medical Solutions USA Inc. on 1 January 2007

**II. RELATED APPEALS AND INTERFERENCES**

There are currently, and have been, no related Appeals or Interferences regarding Application Serial No. 09/742,268

**III. STATUS OF THE CLAIMS**

Claims 1-28 are rejected and the rejection of claims 1-28 are appealed.

**IV. STATUS OF AMENDMENTS**

All amendments were entered and are reflected in the claims included in Appendix I. No amendments were made to the claims after the Final Rejection.

**V. SUMMARY OF CLAIMED SUBJECT MATTER**

Independent claim 1 provides a method for allowing a patient, suffering from a neurological disease and receiving medication for the disease, to self-monitor their actual state. The method includes the step of providing a computer at a location readily accessible to a patient substantially on a daily basis for acquiring information from a patient (Figure 1, element 1; Page 11, lines 5-8). Information is acquired from a patient, via an interactive procedure, wherein the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient (Page 11, line 18 – Page 12, line 13). An expert system is provided that is accessible by the computer (Figure 1, element 10; Page 12, lines 16-17). The acquired patient information is provided to the expert system for processing thereby, and determining, from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication (Page 12, line 14 – Page 13, line 5). The computer is provided with an output device and the quantified indicator is made available to the patient via the output device (Page 13, lines 5-10).

Dependant claim 2 includes the features of independent claim 1 along with the additional feature that the information comprises information characterizing a motor

function of the patient, and wherein the step of acquiring information comprises conducting software-controlled motor function exercises for quantifying at least one of neutral, negative and positive effects of the medication on the patient's state, and quantifying the negative and positive effects for processing by the expert system for use in determining the quantified indicator (Page 5, lines 3-16).

Dependant claim 3 includes the features of independent claim 1 along with the additional feature that the information is information characterizing a verbal communication ability of the patient, and wherein the step of acquiring information comprises acoustically acquiring speech from the patient and assessing the speech with a speech assessment system having speech recognition algorithms and a phonetic data bank to obtain an information value quantifying at least one of neutral, negative and positive effects of the medication on the speech, and supplying the information value to the expert system for processing by the expert system for use in determining the quantified indicator (Page 11, line 18 – Page, line 4).

Dependant claim 4 includes the features of independent claim 1 along with the additional feature that the information is information characterizing cognitive abilities of the patient, and wherein the step of acquiring information comprises generating questions requiring a response from the patient to the respective questions and, from the responses, generating an information value quantifying at least one of neutral, negative and positive effects of the medication on the cognitive abilities of the patient, and supplying the information value to the expert system for processing for use in determining the quantified indicator (Page 12, lines 5-7).

Dependant claim 5 includes the features of dependent claim 4 along with the additional step of acoustically entering the responses from the patient into the computer (Page 11, line 22 – Page 12, line 4).

Dependant claim 6 includes the features of dependent claim 4 along with the additional step of manually entering the responses from the patient into the computer (Page 12, lines 6-7).

Dependant claim 7 includes the features of independent claim 1 along with the additional step of entering additional information characterizing a subjective state of health of the patient during the step of acquiring information (Page 15, line 3).

Dependant claim 8 includes the features of independent claim 1 along with the additional step of obtaining a quantified information value representing the

information acquired in the step of acquiring and storing, after each interactive procedure, as stored information with respect to time, at least one of the quantified indicator, the acquired information and the quantified information value (Page 3, line 20 – Page 4, line 5).

Dependant claim 9 includes the features of dependent claim 8 along with the additional feature that the stored information is provided to the expert system for producing an evaluation regarding dosage of the medication based on the stored information and making the evaluation available to the patient at the output device (Page 12, line 20 – Page 13, line 5).

Dependant claim 10 includes the features of dependent claim 9 along with the additional feature that the stored information includes the quantified indicator, and wherein the expert system produces the evaluation from a chronological analysis of a curve relative to time of the respective quantified indicators obtained after each interactive procedure (Page 7, line 22 – Page 8 line 4).

Dependant claim 11 includes the features of dependent claim 9 along with the additional step of making the chronological curve available to the patient as a displayed curve at the output device (Page 8, lines 4-7).

Dependant claim 12 includes the features of dependent claim 9 along with the additional step of storing the produced evaluation in a memory accessible by the computer (Page 10, lines 10-17).

Dependant claim 13 includes the features of dependent claim 10 along with the additional step of establishing communication between the computer and a physician located remote from the computer, and informing the physician of at least one of the quantified indicator, the evaluation and the information, as transmitted information (Page 12, lines 14-16).

Dependant claim 14 includes the features of dependent claim 13 along with the additional step of transmitting therapy instructions from the physician to the computer based on an examination of the transmitted information, and making the therapy instructions available to the patient at the output device (Page 12, line 17 – Page 13, line 10).

Dependant claim 15 includes the features of independent claim 1 along with the additional feature that the step of determining further comprises formulating the quantified indicator as a number (Page 3, line 20 – Page 4, line 2).

Dependant claim 16 includes the features of independent claim 1 along with the additional feature that the step of determining further comprises formulating the quantified indicator as a statement (Page 4, lines 2-5).

Independent claim 17 provides a system for allowing a patient suffering from a neurological disease and receiving medication for treating the disease, to self-monitor a state of the patient. The system includes a computer readily accessible by the patient disposed at a location at which the patient is present substantially on a daily basis (Figure 1, element 1; Page 11, lines 5-8). At least one software program is installed in the computer able to execute an interactive procedure with the patient to obtain information selected from the group consisting of information characterizing a motor function of the patient, information characterizing verbal communication abilities of the patient, and information characterizing cognitive abilities of the patient (Page 11, line 18 – Page 12, line 13). An input unit is connected to the computer for use by the patient during the interactive procedure for acquiring the information (Figure 1, element 10; Page 12, lines 16-17). An expert system is accessible by the computer able to receive the information and produce a quantified indicator from the information and making the quantified indicator available to the computer (Page 12, line 14 – Page 13, line 5). An output unit is connected to the computer for providing the quantified indicator to the patient (Page 13, lines 5-10).

Dependant claim 18 includes the features of independent claim 17 along with the additional feature that the information is information characterizing a motor function of the patient, and wherein the input unit is a manually operated input unit, and wherein the software program operates the computer to execute motor function test exercises and produces a quantified information value quantifying at least one of neutral, negative and positive effects of the medication on the motor function and makes the quantified information value available to the expert system (Page 5, lines 3-16).

Dependant claim 19 includes the features of independent claim 17 along with the additional feature that the information is information characterizing verbal communication abilities of the patient, and wherein the input unit is an acoustical input unit, and wherein the software program assesses speech made by the patient into the input unit using speech algorithms and a phonetic data bank, and produces a quantified

information value representing the verbal communication abilities, and makes the quantified information value available to the expert system (Page 11, line 18 – Page, line 4).

Dependant claim 20 includes the features of independent claim 17 along with the additional feature that the information is information characterizing cognitive abilities of the patient and wherein the software operates the computer to present questions to the patient and to receive responses from the patient, and produces a quantified information value from the responses quantifying at least one of neutral, negative and positive effects of the medication on the cognitive abilities, and makes the quantified information value available to the expert system (Page 12, lines 5-7).

Dependant claim 21 includes the features of independent claim 17 along with the additional feature of a software program for operating the computer to obtain additional information from the patient characterizing a subjective state of health of the patient (Page 15, line 3).

Dependant claim 22 includes the features of independent claim 17 along with the additional feature that the software program in each interactive procedure produces a quantified information value from the information, and further comprising a memory accessible by the computer and by the expert system for storing, as stored information relative to time, at least one of the quantified indicator, the information and the quantified information value after each interactive procedure (Page 3, line 20 – Page 4, line 5).

Dependant claim 23 includes the features of dependent claim 22 along with the additional feature that the expert system produces an evaluation from the stored information with regard to a dosage of the medication (Page 12, line 20 – Page 13, line 5).

Dependant claim 24 includes the features of dependent claim 23 along with the additional feature that the stored information includes the quantified indicator, and wherein the expert system produces the evaluation by analyzing a chronological curve of respective quantified indicators obtained from successive interactive procedures (Page 7, line 22 – Page 8 line 4).

Dependant claim 25 includes the features of dependent claim 24 along with the additional feature that the computer provides the chronological curve to the output device as a displayed curve (Page 8, lines 4-7).

Dependant claim 26 includes the features of dependent claim 23 along with the additional feature of a transmission link from the computer to an external computer located remotely from the computer for transmitting at least one of the evaluation and the quantified indicator to the external computer (Page 10, lines 10-17).

Dependant claim 27 includes the features of independent claim 17 along with the additional feature that the software operates the computer to formulate the quantified indicator as a number (Page 3, line 20 – Page 4, line 2).

Dependant claim 28 includes the features of independent claim 17 along with the additional feature that the software operates the computer to formulate the quantified indicator as a statement (Page 4, lines 2-5).

#### **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 6,354,299) in view of Kaufman et al. (US 5,868,135).

#### **VII. ARGUMENT**

Fischell and Kaufman et al., when taken alone or in any combination, do not make the present claimed invention unpatentable. Thus, reversal of the Final Rejection (hereinafter termed “rejection”) of claims 1-28 under section 35 U.S.C. § 103(a) is respectfully requested.

#### **Overview of the Cited References**

Fischell describe an “implantable device incorporating an acoustic transducer allow[ing] information and alerts to be communicated from the device to a patient...[T]he acoustic transducer is used in cooperation with an implantable closed-loop system for the treatment of certain neurological disorders such as epilepsy, migraine headaches and Parkinson’s disease, to warn the patient of an imminent seizure or other episode, to provide information to the patient on the state of the implantable apparatus, and to provide reminders and other information to the patient” (Abstract).

Kaufman et al. describe a system “for interactively assisting a patient. The system includes a speech synthesizer and recognition unit coupled to a programmed computer. The computer can keep track of a medication and diagnostic testing schedule...In accordance with a predetermined schedule, the system verbally communicates with the patient, prompts the patient through the various steps necessary to carry out the diagnostic testing and further prompts the patient at appropriate times for taking medication...The system

also provides access to a telecommunication link in response to verbal requests of the patient" (Abstract).

**Rejection of Claims 1-28 under 35 USC 103(a)**  
**over Fischell et al. (U.S. Patent No. 5,962,926)**  
**in view of Kaufman et al (U.S. Patent No. 5,868,135)**

Reversal of the rejection of claims 1-28 under 35 U.S.C. 103(a) as being unpatentable over of U.S. Patent 6,354,299 issued to Fischell et al. in view of U.S. Patent 5,868,135 issued to Kaufman et al. is respectfully requested because the rejection makes crucial errors in interpreting the cited reference. The rejection erroneously states that claims 1-28 are made unpatentable by Fischell et al. in view of Kaufman et al.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the examiner to establish a factual basis to support the legal conclusion of obviousness. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed.Cir. 1988). In so doing, the Examiner is expected to make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (CCPA 1966), and to provide a reason why one having ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion, or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed.Cir. 1988), *cert. denied*, 488 U.S. 825 (1988); *Ashland Oil Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 28, 293, 227 USPQ 657, 664 (Fed.Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986); *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed.Cir. 1984). These showings by the Examiner are an essential part of complying with the burden of presenting a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed.Cir. 1992).

**CLAIMS 1, 5, 6, 7, 8, 12, 15 and 16**

Independent claim 1 recites a "method for allowing a patient, suffering from a neurological disease and receiving medication for said disease, to **self-monitor** the patient's **actual state**". Fischell is concerned with a wholly unrelated method of monitoring a patient. Unlike the present claimed invention, Fischell describes an intracranial control module with a remote sensor/actuator device (Col. 6, line 49 – Col. 7, line 3). The sensors detect blood pressure levels, pain signals transmitted by the brain and precursors for epileptic seizures and the control modules reduces blood pressure, reduces the perception of pain in the brain and can stop an epileptic seizure. Essentially, Fischell is concerned with a system that is implanted within a patient and automatically monitors a patient's internal



indicators to provide relief when danger is detected. Thus, Fischell is fundamentally different than the present claimed invention, as Fischell is concerned with **automatically** preventing seizures using an intracranial implant and the present claimed invention is concerned with **self-monitoring** the actual state of a patient who is receiving medication for a neurological disease.

Specifically, the present claimed invention discloses "acquiring information, via an interactive procedure, from a patient wherein the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient". Fischell fails to provide any 35 USC 112 compliant enabling disclosure of the present claimed feature. Fischell, as described above, automatically monitors a patient's internal indicators (such as blood pressure, nervous stimuli and precursors). In contrast, the present claimed invention is concerned with acquiring information by using interactive procedures. Specifically, as stated on page 3 of the Specification, "the patient must interactively communicate with the computer device". Thus, the interactive procedure occurs between the patient and a computer in order to allow the patient to provide (communicate) information to the computer. In this way, the patient can interactively provide information which is evaluated and enables a patient (not a device as in Fischell) to self-monitor their own actual state. Thus, Fischell is fundamentally different than the present claimed invention, as to acquire information Fischell is concerned with a device for **automatically monitoring** a patient's internal indicators using an implantable device and the present claimed invention is concerned with monitoring a patient via an **interactive procedure**. In Fischell, there is no "interactive procedure" as claimed in the present invention.

Additionally, Fischell describes a speech synthesizer to create voice announcements for one way communication with the patient (Col. 15, line 57 – Col. 16, line 6). In contrast, the present claimed invention is concerned with acquiring information by using interactive procedures that involve two way communications. Thus, Fischell is fundamentally different than the present claimed invention, as Fischell is concerned with a **one way communication scheme** to notify the patient of reminders and the present claimed invention is concerned with a **two way interactive procedure** to acquire information from the patient which is provided to an "expert system" that processes the acquired information to "determine...at least one quantified indicator describing the state of the patient". Fischell neither discloses nor suggests this feature or any structural elements that are able to produce the claimed "quantified indicator" that is used in self-monitoring the patient's actual state.

Additionally, Fischell is concerned with monitoring values such as blood pressure, nervous stimuli and other precursors of epileptic seizure. In contrast, the present claimed invention is concerned with acquiring information about motor function, verbal communication ability and cognitive abilities. Thus, it is respectfully submitted that Fischell does not provide any structure that is able to interactively acquire information characterizing motor skills, verbal ability and cognitive ability. Rather, the Fischell system is internal and monitors internal physiological indicators of the patient without verbal responses. Unlike Fischell, the present claimed acquisition of information about the motor skills, verbal communication ability and cognitive ability provides a baseline indicator to the patient regarding how well the medication being taken is working and whether or not the dosage should be changed. The claimed "quantified indicator" allows a patient to advantageously self-monitor their actual state in view of the medication being taken. Thus, Fischell is fundamentally different than the present claimed invention, as Fischell is concerned with monitoring internal physiological indicators and **NOT** interactively acquiring information characterizing the patient's motor skills, verbal communication ability and cognitive ability as claimed in the present claimed invention.

Furthermore, Fischell fails to disclose or suggest "providing said acquired patient information to said expert system for processing thereby, and determining, from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication". Fischell neither disclose nor suggest this feature and, in view of the objective and operation of the Fischell system, would not need to produce the claimed indicator. As describe above, Fischell is concerned with providing **instant medical responses** to the monitored internal physiological indicators. Accordingly, as Fischell is concerned with instant action, Fischell is not concerned with sending the acquired patient information to an expert system for processing as in the present claimed invention. Thus, Fischell is fundamentally different than the present claimed invention, as Fischell is concerned with providing **instant relief** based on the received patient information. In contrast, the present claimed invention is concerned with providing the patient information **to an expert system for processing** and producing a quantified indicator which is output by an output device and which enables a patient to self-monitor their own progress on a specific medication. Moreover, the instantaneous response of the Fischell system would be rendered useless if the Fischell implant had to "provide said computer with an output device and making said quantified indicator available to the patient via said output device" as in the present claimed invention.

Kaufman, adds nothing when taken in combination with Fischell that provides 35 USC 112 compliant enabling disclosure of the present claimed system. Kaufman (with Fischell) neither disclose nor suggest "acquiring information, via an interactive procedure,

from a patient wherein the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient" as described in the present claimed invention. Kaufman provides a system for assisting patients who are convalescing or injured, prompting the patient through steps to carry out **diagnostic testing** and **when to take medication**. The system of Kaufman is designed primarily to acquire information such as blood pressure, heart rate, body temperature and possibly blood gas levels. In contrast, the present claimed invention is concerned with an interactive procedure for acquiring information about motor function, verbal communication ability and cognitive abilities in order to evaluate how a patient who suffers from a neurological disease is reacting to the prescribed medication. Unlike the present claimed invention, Kaufman (similarly to Fischell) is merely concerned with acquiring medical indicators describing **blood tests**. This is fundamentally different from the present claimed invention which acquires information describing the patient's motor skills, verbal communication ability and cognitive ability. Kaufman (with Fischell) neither disclose nor suggest an equivalent method or structural elements that are able to perform the present claimed method.

Additionally, Kaufman et al. are not concerned with an interactive procedure as in the present claimed invention. Rather, Kaufman et al. are concerned with prompting the patient through the steps of diagnostic testing and reminding the patient to take medication. In contrast, the present claimed invention is concerned with acquiring information through an interactive procedure. Thus, Kaufman et al. are fundamentally different than the present claimed invention, as Kaufman et al. are concerned with a **one way communication** prompting the patient to take action and the present claimed invention is concerned with a **two way interactive communication** to acquire information from the patient.

In addition, Kaufman, similarly to Fischell, neither disclose nor suggest "providing said acquired patient information to said expert system for processing thereby, and determining, from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication" as in the present claimed invention. Kaufman provides a modem to transmit patient activity and results to a remote medical center for analysis. This analysis can then be used to determine whether changes needed to be made to the patient's medication (Col. 5, lines 21-30). In contrast, the present claimed invention provides the acquired patient information to an expert system to create a quantified indicator describing the state of patient suffering. In this way, the indicator informs the patient about their own actual state. Thus, Kaufman is fundamentally different than the present claimed invention, as Kaufman is concerned with providing a remote medical center with the acquired patient physiological information **for**

**analyzing whether the patient's medications need to be altered** and the present claimed invention provides an expert facility with the acquired patient information, including information acquired by verbal response, **for determining a quantified indicator describing the state of the patient suffering** and how well the patient is responding to the medication and whether or not the patient is functioning normally while on the medication. Patient verbal responses provide valuable input to the expert system.

Furthermore, Kaufman (with Fischell), neither disclose nor suggest "providing said computer with an output device and making said quantified indicator available to the patient via said output device" as in the present claimed invention. As described above, Kaufman is not concerned with creating a quantified indicator to describe to the patient their actual state in view of the acquired information characterizing motor function, verbal communication skills and cognitive ability. The remote facility of Kaufman merely uses the acquired patient physiological information to analyze whether the patient's medications need to be modified. The expert system of Kaufman et al. is not concerned with creating an indicator, based on the acquired patient information, to transmit back to the patient for the purpose of informing them of their actual state. At most, the expert facility of Kaufman would merely send advised changes in medication to a medication dispensing facility—not the patient. Thus, Kaufman is wholly unlike the present claimed invention, as Kaufman et al. are not concerned with **providing the indicator describing the state of the patient suffering to the patient** as in the present claimed invention.

In addition, it would not be obvious to combine the systems of Fischell and Kaufman, as both are concerned with entirely different testing and/or monitoring schemes. Specifically, Fischell is concerned with an implantable device that can monitor a patient's physiological indicators and Kaufman is concerned with external methods of testing a patient's physiological indicators. Thus, Fischell is fundamentally different from Kaufman, as Fischell is concerned with an **implantable** medical testing device and Kaufman is concerned with **external** testing devices. These systems of evaluation are incompatible in view of Fischell's requirement to provide instantaneous relief to a patient when certain physiological indicators are detected such as prevent seizures and preventing pain by inactivating pain centers in the brain. Additionally, Fischell is concerned with automatically monitoring a patient's medical indicators using the implantable medical testing device. In contrast, Kaufman is concerned with a system that guides the patient through the steps of testing themselves. Thus, Fischell is fundamentally different than Kaufman, as Fischell is concerned with **automatically monitoring** the patient and Kaufman is concerned with **interacting with** the patient to obtain the physiological data. Therefore, there is no reason or motivation to combine the systems of Fischell and

Kaufman for they are concerned with totally different methods of acquiring patient information.

Furthermore, it would not be obvious to combine the systems of Fischell and Kaufman, as both are concerned with entirely different uses for data that is obtained. Specifically, Fischell is concerned with immediately providing relief to the patient based on the acquired patient information. In contrast, Kaufman is concerned with transmitting the acquired patient information to a medical facility to determine whether the medication scheme should be changed. Thus, Fischell is fundamentally different to, and incompatible with, Kaufman et al., as Fischell et al are concerned with **immediate relief** and Kaufman et al. are concerned with **delayed relief** provided by the medical facility. The goal of immediate relief of Fischell is incompatible with the delayed relief or suggestions provided by the Kaufman system. Therefore, there is no reason or motivation to combine the systems of Fischell and Kaufman et al. for they are concerned with totally different methods of relief.

However, even if one were to combine the systems of Fischell and Kaufman the combined system would not provide any 35 USC 112 compliant enabling disclosure of the present claimed invention. Specifically, Fischell with Kaufman neither discloses nor suggests a "method for allowing a patient, suffering from a neurological disease and receiving medication for said disease, to self-monitor the patient's actual state" such that the patient may be provided with a "quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication". The combination of Fischell system with the Kaufman system would result in an implantable device for automatically monitoring physiological values and providing relief to the patient in response to the values. Additionally, the combined system would seek to send these values to a remote computer system to determine what, if any, changes to medication could be realized based on these physiological values. Thus, it is respectfully submitted that the combination of Fischell and Kaufman, would not produce a method that **allows a patient to self-monitor their actual state** based on interactive verbal response, as in the present claimed invention.

Moreover, the combination of the Fischell system and the Kaufman system neither discloses nor suggest "acquiring information, via an interactive procedure, from a patient wherein the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient" as in the present claimed system. Rather, both Fischell and Kaufman are concerned with monitoring physiological values of a patient and responding to those

physiological values. This is fundamentally different from the present claimed invention. Fischell is concerned with internal medical (physiological) indicators and Kaufman is concerned with blood related (physiological) indicators. Neither Fischell nor Kaufman are concerned with information characterizing motor function, verbal communication ability or cognitive ability as in the present claimed invention. Thus, it is respectfully submitted that the combination, similar to the individual systems of Fischell and Kaufman et al., is not concerned with **acquiring information from the patient characterizing motor function, verbal communication ability or cognitive ability to determine a quantified indicator** describing the state of the patient's suffering as in the present claimed invention. Consequently, it is respectfully requested that the rejection of claim 1 under 35 USC 103(a) be withdrawn.

Claims 5, 6, 7, 8, 15 and 16 are dependent on independent claim 1 and are considered patentable for the reasons presented above with respect to independent claim 1. Consequently, it is respectfully requested that the rejection of claims 5, 6, 7, 8, 15 and 16 be withdrawn.

#### CLAIM 2

Claim 2 is dependent on independent claim 1 and is considered patentable for the reasons presented above with respect to claim 1. Claim 2 is also considered patentable because Fischell with Kaufman fail to provide any 35 USC 112 compliant enabling disclosure of "wherein the step of acquiring information comprises conducting software-controlled motor function exercises for quantifying at least one of neutral, negative and positive effects of said medication on said patient's state, and quantifying said negative and positive effects for processing by said expert system for use in determining said quantified indicator" as claimed in the present invention. As described above, Fischell is concerned with internal medical indicators and Kaufman is concerned with blood related indicators. Both Fischell and Kaufman et al. are therefore concerned with physiological values obtained directly from the patient's body and **not** concerned with information characterizing motor function, verbal communication ability or cognitive ability as in the present claimed invention. The Rejection cites column 7, lines 1 - 35 of Kaufman as adding the necessary disclosure to Fischell that would make the present claimed invention obvious. Applicant respectfully disagrees. Rather, the cited section of Kaufman describes a storage and delivery unit for different items which includes an indicator that tells the patient to remove a physiological monitoring device such as a blood pressure cuff from the patient's body. There is no 35 USC 112 compliant enabling disclosure of the present claimed "software-controlled motor function exercises for quantifying" the effects of the medication on the patient's state. There is no mention of testing motor skills or any structures able to perform a test of motor skills in either Kaufman alone or in combination

with Fischell. Consequently, withdrawal of the rejection of claim 2 is respectfully requested.

### CLAIM 3

Claim 3 is dependent on independent claim 1 and is considered patentable for the reasons presented above with respect to claim 1. Claim 3 is also considered patentable because Kaufman (with Fischell) neither disclose nor suggests "the step of acquiring information comprises acoustically acquiring speech from said patient and assessing said speech with a speech assessment system having speech recognition algorithms and a phonetic data bank to obtain an information value quantifying at least one of neutral, negative and positive effects of said medication on said speech, and supplying said information value to said expert system for processing by said expert system for use in determining said quantified indicator" as recited in the present claimed invention. The Rejection cites column 4, lines 23 ~ 60 of Kaufman as disclosing the present claimed feature. Applicant respectfully disagrees. Rather, the cited section merely states that the Kaufman system includes an audible alarm that may be controlled by a calendaring unit to ensure that a specified schedule is adhered to. This is fundamentally different from and not equivalent to using "a speech assessment system having speech recognition algorithms and a phonetic data bank" for acquiring data regarding a patient's verbal communication ability to determine if the medication is having any effect thereon. There is nothing in the cited section of Kaufman (or elsewhere) that provides 35 USC 112 compliant enabling disclosure of the present claimed feature. Consequently, withdrawal of the rejection of claim 3 is respectfully requested.

### CLAIM 4

Claim 4 is dependent on claim 1 and is considered patentable for the reasons presented above with respect to claim 1. Claim 4 is also considered patentable because Kaufman (with Fischell) fail to disclose or suggest "the step of acquiring information comprises generating questions requiring a response from said patient to the respective questions and, from said responses, generating an information value quantifying at least one of neutral, negative and positive effects of said medication on said cognitive abilities of the patient, and supplying said information value to said expert system for processing for use in determining said quantified indicator" as in the present claimed invention. The Rejection cites column 3, lines 40 ~ 67 of Fischell as disclosing the present claimed feature. Applicant respectfully disagrees. Rather, the cited section of Fischell describes electrodes that are implanted within the brain that may detect a neurological event that may lead to a seizure for a patient. However, this detection is a physiological value and is not at all related to the "cognitive abilities of the patient" based on questions that have

been interactively presented to the patient and which are answered by the patient as in the present claimed invention. The physiological automatic monitoring of Fischell is not equivalent to determining the cognitive abilities of the patient by the patient interacting with a computer system. Consequently, withdrawal of the rejection of claim 4 is respectfully requested.

#### CLAIMS 9, 11 and 12

Claim 9 is dependent on independent claim 1 and is considered patentable for the reasons presented above with respect to claim 1. Dependant claim 9 is also considered patentable because Fischell with Kaufman fail to disclose or suggest "providing said stored information to said expert system for producing an evaluation regarding dosage of said medication based on said stored information and making said evaluation available to the patient as said output device" as recited in the present claimed invention. Fischell is not concerned with making evaluations or indicators available to the patient but rather is intended to monitor and provide instantaneous relief. Kaufman does determine if a change in medication dosage is needed. However, the determination in Kaufman is based on entirely different and unrelated data than the evaluation made in the present claimed invention. Kaufman determines if the patient's medication scheme needs to be modified using input physiological parameters and communicates any change in dosage to a medical professional. Contrary to the Kaufman, the claimed arrangement acquires information characterizing the motor skills, verbal communication ability and cognitive abilities to see the effect the medication is having by producing a quantified indicator value **to the patient**. Thus, it is respectfully submitted that the combination of the systems of Fischell and Kaufman neither discloses nor suggests making evaluations available to the patient. Consequently, it is respectfully requested that the rejection of claim 9 under 35 USC 103(a) be withdrawn.

Claims 11 and 12 are dependent on claims 1 and 9 and are considered patentable for the reasons presented above with respect to claims 1 and 9. Consequently, withdrawal of the rejection of claims 11 and 12 under 35 USC 103(a) is respectfully requested.

#### CLAIMS 10 and 13

Claim 10 is dependent on claims 1 and 9 and is considered patentable for the reasons presented above with respect to claims 1 and 9. Dependant claim 10 is also considered patentable because Fischell and Kaufman neither disclose nor suggest that "said expert system produces said evaluation from a chronological analysis of a curve relative to time of the respective quantified indicator obtained after each iterative procedure" as recited in the present claimed invention. The Rejection cites column 34, lines 9 - 53 of Fischell as disclosing the present claimed feature. Applicant respectfully submits that there



is nothing in this cited section that enables one reasonably skilled in the art to discern or produce the present claimed feature. Rather, the cited section deals with electrical signals transmission to the implanted device that is used to prevent the neurological event. There is nothing about quantified indicators based on motor skills, verbal communication ability and/or cognitive ability for use in self-monitoring a patient's actual state over time based on a chronological analysis. Consequently, it is respectfully requested that the rejection of claim 10 under 35 USC 103(a) be withdrawn.

Claim 13 is dependent on claims 1 and 10 and is considered patentable for the reasons presented above with respect to claims 1 and 10. Consequently, it is respectfully requested that the rejection of claim 13 under 35 USC 103(a) be withdrawn.

#### CLAIMS 17, 21, 22, 27 and 28

Independent claim 17 recites "A system for allowing a patient suffering from a neurological disease and receiving medication for treating said disease, to self-monitor a state of the patient". Fischell is concerned with a wholly unrelated method of monitoring a patient. Unlike the present claimed invention, Fischell describes an intracranial control module with a remote sensor/actuator device (Col. 6, line 49 – Col. 7, line 3). The sensors detect blood pressure levels, pain signals transmitted by the brain and precursors for epileptic seizures and the control modules reduces blood pressure, reduces the perception of pain in the brain and can stop an epileptic seizure. Essentially, Fischell is concerned with a system that is implanted within a patient and automatically monitors a patient's internal indicators to provide relief when danger is detected. Thus, Fischell is fundamentally different than the present claimed invention, as Fischell is concerned with **automatically** preventing seizures using an intracranial implant and the present claimed invention is concerned with **self-monitoring** the actual state of a patient who is receiving medication for a neurological disease.

Specifically, the present claimed invention discloses "acquiring information, via an interactive procedure, from a patient wherein the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient". Fischell fails to provide any 35 USC 112 compliant enabling disclosure of the present claimed feature. Fischell, as described above, automatically monitors a patient's internal indicators (such as blood pressure, nervous stimuli and precursors). In contrast, the present claimed invention is concerned with acquiring information by using interactive procedures. Specifically, as stated on page 3 of the Specification, "the patient must interactively communicate with the computer device". Thus, the interactive procedure occurs between the patient and a computer in order to allow

the patient to provide (communicate) information to the computer. In this way, the patient can interactively provide information which is evaluated and enables a patient to self-monitor their own actual state. Thus, Fischell is fundamentally different than the present claimed invention, as to acquire information Fischell is concerned with **automatically monitoring** a patient's internal indicators using an implantable device and the present claimed invention is concerned with monitoring a patient via an **interactive procedure**. In Fischell, there is no "interactive procedure" as claimed in the present invention.

Additionally, Fischell describes a speech synthesizer to create voice announcements for one way communication with the patient (Col. 15, line 57 – Col. 16, line 6). In contrast, the present claimed invention is concerned with acquiring information by using interactive procedures that involve two way communications. Thus, Fischell is fundamentally different than the present claimed invention, as Fischell is concerned with a **one way communication scheme** to notify the patient of reminders and the present claimed invention is concerned with a **two way interactive procedure** to acquire information from the patient which is provided to an "expert system" that processes the acquired information to "determine...at least one quantified indicator describing the state of the patient". Fischell neither discloses nor suggests this feature or any structural elements that are able to produce the claimed "quantified indicator" that is used in self-monitoring the patient's actual state.

Additionally, Fischell is concerned monitoring values such as blood pressure, nervous stimuli and other precursors of epileptic seizure. In contrast, the present claimed invention is concerned with acquiring information about motor function, verbal communication ability and cognitive abilities. Thus, it is respectfully submitted that Fischell does not provide any structure that is able to interactively acquire information characterizing motor skills, verbal ability and cognitive ability. Rather, the Fischell system is internal and monitors internal physiological indicators of the patient. Unlike Fischell, the present claimed acquisition of information about the motor skills, verbal communication ability and cognitive ability provides a baseline indicator to the patient regarding how well the medication being taken is working and whether or not the dosage should be changed. The claimed "quantified indicator" allows a patient to advantageously self-monitor their actual state in view of the medication being taken. Thus, Fischell is fundamentally different than the present claimed invention, as Fischell is concerned with monitoring internal physiological indicators and **NOT** interactively acquiring information characterizing the patient's motor skills, verbal communication ability and cognitive ability as claimed in the present claimed invention.

Furthermore, Fischell fails to disclose or suggest "providing said acquired patient information to said expert system for processing thereby, and determining, from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication". Fischell neither disclose nor suggest this feature and, in view of the objective and operation of the Fischell system, would not need to produce the claimed indicator. As describe above, Fischell is concerned with providing **instant medical responses** to the monitored internal physiological indicators. Accordingly, as Fischell is concerned with instant action, Fischell is not concerned with sending the acquired patient information to an expert system for processing as in the present claimed invention. Thus, Fischell is fundamentally different than the present claimed invention, as Fischell is concerned with providing **instant relief** based on the received patient information and the present claimed invention is concerned with providing the patient information **to an expert system for processing** and producing a quantified indicator which is output by an output device and which enables a patient to self-monitor their own progress on a specific medication. Moreover, the instantaneous response of the Fischell system would be rendered useless if the Fischell implant had to "provide said computer with an output device and making said quantified indicator available to the patient via said output device" as in the present claimed invention.

Kaufman, adds nothing when taken in combination with Fischell that provides 35 USC 112 compliant enabling disclosure of the present claimed system. Kaufman (with Fischell) neither disclose nor suggest "acquiring information, via an interactive procedure, from a patient wherein the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient" as described in the present claimed invention. Kaufman provides a system for assisting patients who are convalescing or injured, prompting the patient through steps to carry out **diagnostic testing** and **when to take medication**. The system of Kaufman is designed primarily to acquire information such as blood pressure, heart rate, body temperature and possibly blood gas levels. In contrast, the present claimed invention is concerned with an interactive procedure for acquiring information about motor function, verbal communication ability and cognitive abilities in order to evaluate how a patient who suffers from a neurological disease is reacting to the prescribed medication. Kaufman, similarly to Fischell, and unlike the present claimed invention, is merely concerned with acquiring medical indicators describing **blood tests**. This is fundamentally different from the present claimed invention which acquires information describing the patient's motor skills, verbal communication ability and cognitive ability. Kaufman (with Fischell) neither disclose nor suggest an equivalent method or structural elements that are able to perform the present claimed method.

Additionally, Kaufman et al. are not concerned with an interactive procedure as in the present claimed invention. Rather, Kaufman et al. are concerned with prompting the patient through the steps of diagnostic testing and reminding the patient to take medication. In contrast, the present claimed invention is concerned with acquiring information through an interactive procedure. Thus, Kaufman et al. are fundamentally different than the present claimed invention, as Kaufman et al. are concerned with a **one way communication** prompting the patient to take action and the present claimed invention is concerned with a **two way interactive communication** to acquire information from the patient.

In addition, Kaufman, similarly to Fischell, neither disclose nor suggest "providing said acquired patient information to said expert system for processing thereby, and determining, from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication" as in the present claimed invention. Kaufman provides a modem to transmit patient activity and results to a remote medical center for analysis. This analysis can then be used to determine whether changes needed to be made to the patient's medication (Col. 5, lines 21-30). In contrast, the present claimed invention provides the acquired patient information to an expert system to create a quantified indicator describing the state of patient suffering. In this way, the indicator can relate to the patient their own actual state. Thus, Kaufman is fundamentally different than the present claimed invention, as Kaufman is concerned with providing a remote medical center with the acquired patient physiological information for **analyzing whether the patient's medications need to be altered** and the present claimed invention provides an expert facility with the acquired patient information for **determining a quantified indicator describing the state of the patient suffering** and how well the patient is responding to the medication and whether or not the patient is functioning normally while on the medication.

Furthermore, Kaufman (with Fischell), neither disclose nor suggest "providing said computer with an output device and making said quantified indicator available to the patient via said output device" as in the present claimed invention. As described above, Kaufman is not concerned with creating a quantified indicator to describe to the patient their actual state in view of the acquired information characterizing motor function, verbal communication skills and cognitive ability. The remote facility of Kaufman merely uses the acquired patient physiological information to analyze whether the patient's medications need to be modified. The expert system of Kaufman et al. is not at all concerned with creating an indicator, based on the acquired patient information, to transmit back to the patient for the purpose of informing them of their actual state. At most, the expert facility of Kaufman would merely send advised changes in medication to a medication dispensing

facility—not the patient. Thus, Kaufman is wholly unlike the present claimed invention, as Kaufman et al. are not concerned with **providing the indicator describing the state of the patient suffering to the patient** as in the present claimed invention.

In addition, it would not be obvious to combine the systems of Fischell and Kaufman, as both are concerned with entirely different testing and/or monitoring schemes. Specifically, Fischell is concerned with an implantable device that can monitor a patient's physiological indicators and Kaufman is concerned with external methods of testing a patient's physiological indicators. Thus, Fischell is fundamentally different from Kaufman, as Fischell is concerned with an **implantable** medical testing device and Kaufman is concerned with **external** testing devices. These manners of evaluation are incompatible in view of Fischell's requirement to provide instantaneous relief to a patient when certain physiological indicators are detected such as prevent seizures and preventing pain by inactivating pain centers in the brain. Additionally, Fischell is concerned with automatically monitoring a patient's medical indicators using the implantable medical testing device. In contrast, Kaufman is concerned with a system that guides the patient through the steps of testing themselves. Thus, Fischell is fundamentally different than Kaufman, as Fischell is concerned with **automatically monitoring** the patient and Kaufman is concerned with **interacting with** the patient to obtain the physiological data. Therefore, there is no reason or motivation to combine the systems of Fischell and Kaufman for they are concerned with totally different methods of acquiring patient information.

Furthermore, it would not be obvious to combine the systems of Fischell and Kaufman, as both are concerned with entirely different uses for any data that is obtained. Specifically, Fischell is concerned with immediately providing relief to the patient based on the acquired patient information. In contrast, Kaufman is concerned with transmitting the acquired patient information to a medical facility to determine whether the medication scheme should be changed. Thus, Fischell is fundamentally different than Kaufman et al., as Fischell et al. are concerned with **immediate relief** and Kaufman et al. are concerned with **delayed relief** provided by the medical facility. The goal of immediate relief of Fischell is incompatible with the delayed relief or suggestions provided by the Kaufman system. Therefore, there is no reason or motivation to combine the systems of Fischell and Kaufman et al. for they are concerned with totally different methods of relief.

However, even if one were to combine the systems of Fischell and Kaufman the combined system would not provide any 35 USC 112 compliant enabling disclosure of the present claimed invention. Specifically, Fischell with Kaufman neither discloses nor suggests a "method for allowing a patient, suffering from a neurological disease and

receiving medication for said disease, to self-monitor the patient's actual state" such that the patient may be provided with a "quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication". The combination of Fischell system with the Kaufman system would result in an implantable device for automatically monitoring physiological values and providing relief to the patient in response to the values. Additionally, the combined system would seek to send these values to a remote computer system to determine what, if any, changes to medication could be realized based on these physiological values. Thus, it is respectfully submitted that the combination of Fischell and Kaufman, would not produce a method that **allows a patient to self-monitor their actual state**, as in the present claimed invention.

Moreover, the combination of the Fischell system and the Kaufman system neither discloses nor suggest "acquiring information, via an interactive procedure, from a patient wherein the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient" as in the present claimed system. Rather, both Fischell and Kaufman are concerned with monitoring physiological values of a patient and responding to those physiological values. This is fundamentally different from the present claimed invention. Fischell is concerned with internal medical (physiological) indicators and Kaufman is concerned with blood related (physiological) indicators. Neither Fischell nor Kaufman are concerned with information characterizing motor function, verbal communication ability or cognitive ability as in the present claimed invention. Thus, it is respectfully submitted that the combination, similar to the individual systems of Fischell and Kaufman et al., is not concerned with **acquiring information from the patient characterizing motor function, verbal communication ability or cognitive ability to determine a quantified indicator** describing the state of the patient's suffering as in the present claimed invention. Consequently, it is respectfully requested that the rejection of claim 17 under 35 USC 103(a) be withdrawn.

Claims 21, 22, 27 and 28 are dependent on independent claim 17 and are considered patentable for the reasons presented above with respect to independent claim 17. Consequently, withdrawal of the rejection of claims 21, 22, 27 and 28 under 35 USC 103(a) is respectfully requested.

#### CLAIM 18

Claim 18 is dependent on independent claim 17 and is considered patentable for the reasons presented above with respect to claim 17. Claim 18 is also considered patentable because Fischell with Kaufman fail to provide any 35 USC 112 compliant

enabling disclosure of "wherein said input is a manually operated input and wherein said software operates said computer to execute motor function test exercises and produces a quantified information value quantifying at least one of neutral, negative and positive effects of said medication on said motor function and makes said quantified information value available to said expert system" as claimed in the present invention. As described above, Fischell is concerned with internal medical indicators and Kaufman is concerned with blood related indicators. Both Fischell and Kaufman et al. are therefore concerned with physiological values obtained directly from the patient's body and **not** concerned with information characterizing motor function, verbal communication ability or cognitive ability as in the present claimed invention. The Rejection cites column 21, lines 19 – 67 of Fischell as providing enabling disclosure that would make the present claimed invention obvious. Applicant respectfully disagrees. Rather, the cited section of Fischell merely describes signal processing methods that may be run within a digital signal processor that may be used to record a neurological event that records EEG and other data that is present before, during and after a neurological event. There is nothing in this cited section that provides enabling disclosure of "a manually operated input device" that is used by a patient to performed computer controlled motor function test exercises to determine the effects medication is having on the patient's actual state. There is no 35 USC 112 compliant enabling disclosure of the present claimed "software-controlled motor function exercises for quantifying" the effects of the medication on the patient's state. There is no mention of testing motor skills or any structures able to perform a test of motor skills in either Kaufman alone or in combination with Fischell. Consequently, withdrawal of the rejection of claim 18 is respectfully requested.

#### CLAIM 19

Claim 19 is dependent on independent claim 17 and is considered patentable for the reasons presented above with respect to claim 17. Claim 19 is also considered patentable because Kaufman (with Fischell) neither disclose nor suggests "wherein said input unit is an acoustical input unit, and wherein said software program assesses speech made by said patient into said input unit using speech algorithms and a phonetic data bank, and produces a quantified information value representing said verbal communication abilities, and makes said quantified information value available to said expert system" as recited in the present claimed invention. The Rejection cites column 6, lines 61 – 67 of Kaufman as disclosing the present claimed feature. Applicant respectfully disagrees. Rather, the cited section merely states that the Kaufman system includes a voice recognition module to allow for a patient to input instructions. However, there is nothing further provided in the cited section (or elsewhere) in Kaufman that describes the audible input of the patient and how the Kaufman system responds thereto. Even in view of the audible input by a patient, there

is nothing in Kaufman (with Fischell) that describes using "speech assessment software program to assess speech made by the patient using speech algorithms and a phonetic database as in the present claimed invention in order to "produce a quantified information value representing said verbal communication abilities" of the patient in view of the medication being taken by the patient. There is nothing in the cited section of Kaufman (or elsewhere) that provides 35 USC 112 compliant enabling disclosure of the present claimed feature. Consequently, withdrawal of the rejection of claim 19 is respectfully requested.

#### CLAIM 20

Claim 20 is dependent on claim 17 and is considered patentable for the reasons presented above with respect to claim 17. Claim 20 is also considered patentable because Kaufman (with Fischell) fail to disclose or suggest that "said software operates said computer to present questions to said patient and to receive responses from said patient, and produces a quantified information value from said responses quantifying at least one of neutral, negative and positive effects of said medication on said cognitive abilities, and makes said quantified information value available to said expert system" as in the present claimed invention. The Rejection cites column 5, lines 14 - 45 of Kaufman as disclosing the present claimed feature. Applicant respectfully disagrees. Rather, the cited section of Kaufman describes the manner in which the system communicates with a remote computer that is charged with evaluating the physiological parameters detected by the Kaufman system. However, this detection is a physiological value and is not at all related to the "cognitive abilities of the patient" based on questions that have been interactively presented to the patient and which are answered by the patient as in the present claimed invention. The physiological automatic monitoring of Fischell is not equivalent to determining the cognitive abilities of the patient by the patient interacting with a computer system. Consequently, withdrawal of the rejection of claim 20 is respectfully requested.

#### CLAIMS 23 and 26

Claim 23 is dependent on independent claim 17 and is considered patentable for the reasons presented above with respect to claim 17. Dependant claim 23 is also considered patentable because Fischell with Kaufman fail to disclose or suggest "wherein said expert system produces an evaluation with regard to dosage of said medication" as recited in the present claimed invention. Fischell is not concerned with making evaluations or indicators available to the patient but rather is intended to monitor and provide instantaneous relief. Kaufman does determine if a change in medication dosage is needed. However, the determination in Kaufman is based on entirely different and unrelated data than the evaluation made in the present claimed invention. Kaufman determines if the patient's



medication scheme needs to be modified using input physiological parameters and communicates any change in dosage to a medical professional. Contrary to the Kaufman, the claimed arrangement acquires information characterizing the motor skills, verbal communication ability and cognitive abilities to see the effect the medication is having by producing a quantified indicator value **to the patient**. Thus, it is respectfully submitted that the combination of the systems of Fischell and Kaufman neither discloses nor suggests making evaluations available to the patient. Consequently, it is respectfully requested that the rejection of claim 23 under 35 USC 103(a) be withdrawn.

Claim 26 is dependent on claims 17 and 23 and is considered patentable for the reasons presented above with respect to claims 17 and 23. Consequently, it is respectfully requested that the rejection of claim 26 under 35 USC 103(a) be withdrawn.

#### CLAIMS 24 and 25

Claim 24 is dependent on claims 17 and 23 and is considered patentable for the reasons presented above with respect to claims 17 and 23. Dependant claim 24 is also considered patentable because Fischell and Kaufman neither disclose nor suggest that "wherein said expert system produces said evaluation by analyzing a chronological curve of respective quantified indicators obtained from successive interactive procedures" as recited in the present claimed invention. The Rejection cites column 21, lines 35 – 67 of Fischell as disclosing the present claimed feature. Applicant respectfully submits that there is nothing in this cited section that enables one reasonably skilled in the art to discern or produce the present claimed feature. Rather, the cited section deals with electrical signal transmission to the implanted device that is used to prevent the neurological event. There is nothing about quantified indicators based on motor skills, verbal communication ability and/or cognitive ability for use in self-monitoring a patient's actual state over time based on a chronological analysis. Consequently, it is respectfully requested that the rejection of claim 10 under 35 USC 103(a) be withdrawn.

Claim 25 is dependent on claims 17 and 24 and is considered patentable for the reasons presented above with respect to claims 17 and 24. Consequently, it is respectfully requested that the rejection of claim 25 under 35 USC 103(a) be withdrawn.

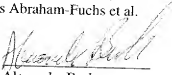
#### VIII. CONCLUSION

Fischell and Kaufman et al., when taken alone or in combination, neither disclose nor suggest that "to self-monitor the patient's actual state" as recited in claim 1 and similarly in claim 17 of the present claimed invention. Additionally, Fischell and Kaufman et al., when taken alone or in combination, neither disclose nor suggest that "acquiring information, via an interactive procedure, from a patient" as recited in claim 1 and similarly

in claim 17 of the present claimed invention. Furthermore, Fischell and Kaufman et al., when taken alone or in combination, neither disclose nor suggest that "the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient" as recited in claim 1 and similarly in claim 17 of the present claimed invention. Even further, Fischell and Kaufman et al., when taken alone or in combination, neither disclose nor suggest that "providing said acquired patient information to said expert system for processing thereby, and determining, from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication" as recited in claim 1 and similarly in claim 17 of the present claimed invention. In addition, Fischell and Kaufman et al., when taken alone or in combination, neither disclose nor suggest that "making said quantified indicator available to the patient" as recited in claim 1 and similarly in claim 17 of the present claimed invention.

Accordingly it is respectfully submitted that the rejection of Claims 1-28 should be reversed.

Respectfully submitted,  
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**APPENDIX I - APPEALED CLAIMS**

1. (Previously Presented) A method for allowing a patient, suffering from a neurological disease and receiving medication for said disease, to self-monitor the patient's actual state, comprising the steps of:

- providing a computer at a location readily accessible to a patient substantially on a daily basis for acquiring information from a patient;

- acquiring information, via an interactive procedure, from a patient wherein the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient;

- providing an expert system accessible by the computer;

- providing said acquired patient information to said expert system for processing thereby, and determining, from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication; and

- providing said computer with an output device and making said quantified indicator available to the patient via said output device.

2. (Previously Presented) A method as claimed in claim 1 wherein said information comprises information characterizing a motor function of said patient, and wherein the step of acquiring information comprises conducting software-controlled motor function exercises for quantifying at least one of neutral, negative and positive effects of said medication on said patient's state, and quantifying said negative and positive effects for processing by said expert system for use in determining said quantified indicator.

3. (Previously Presented) A method as claimed in claim 1 wherein said information is information characterizing a verbal communication ability of said patient, and wherein the step of acquiring information comprises acoustically acquiring speech from said patient and assessing said speech with a speech assessment system having speech recognition algorithms and a phonetic data bank to obtain an information value quantifying at least one of neutral, negative and positive effects of said medication on said speech, and supplying said information value to said expert system for processing by said expert system for use in determining said quantified indicator.

4. (Previously Presented) A method as claimed in claim 1 wherein said information is information characterizing cognitive abilities of the patient, and wherein

the step of acquiring information comprises generating questions requiring a response from said patient to the respective questions and, from said responses, generating an information value quantifying at least one of neutral, negative and positive effects of said medication on said cognitive abilities of the patient, and supplying said information value to said expert system for processing for use in determining said quantified indicator.

5. (Previously Presented) A method as claimed in claim 4 comprising the step of acoustically entering said responses from said patient into said computer.

6. (Previously Presented) A method as claimed in claim 4 comprising the step of manually entering said responses from said patient into said computer.

7. (Previously Presented) A method as claimed in claim 1 comprising the step of entering additional information characterizing a subjective state of health of said patient during said step of acquiring information.

8. (Previously Presented) A method as claimed in claim 1 further comprising the step of obtaining a quantified information value representing said information acquired in said, step of acquiring and storing, after each interactive procedure, as stored information with respect to time, at least one of said quantified indicator, said acquired information and said quantified information value.

9. (Previously Presented) A method as claimed in claim 8 comprising providing said stored information to said expert system for producing an evaluation regarding dosage of said medication based on said stored information and making said evaluation available to the patient at said output device.

10. (Previously Presented) A method as claimed in claim 9 wherein said stored information includes said quantified indicator, and wherein said expert system produces said evaluation from a chronological analysis of a curve relative to time of the respective quantified indicators obtained after each interactive procedure.

11. (Previously Presented) A method as claimed in claim 9 further comprising the step of making the chronological curve available to said patient as a displayed curve at said output device.

12. (Previously Presented) A method as claimed in claim 9 further comprising the step of storing said produced evaluation in a memory accessible by said computer.

13. (Previously Presented) A method as claimed in claim 10 further comprising the step of establishing communication between said computer and a physician located remote from said computer, and informing said physician of at least one of said quantified indicator, said evaluation and said information, as transmitted information.

14. (Previously Presented) A method as claimed in claim 13 further comprising the step of transmitting therapy instructions from said physician to said computer based on an examination of said transmitted information, and making said therapy instructions available to the patient at said output device.

15. (Previously Presented) A method as claimed in claim 1 wherein said step of determining further comprises formulating said quantified indicator as a number.

16. (Previously Presented) A method as claimed in claim 1 wherein said step of determining further comprises formulating said quantified indicator as a statement.

17. (Previously Presented) A system for allowing a patient suffering from a neurological disease and receiving medication for treating said disease, to self-monitor a state of the patient, comprising:

- a computer readily accessible by the patient disposed at a location at which said patient is present substantially on a daily basis;

- at least one software program installed in said computer able to execute an interactive procedure with said patient to obtain information selected from the group consisting of information characterizing a motor function of the patient, information characterizing verbal communication abilities of the patient, and information characterizing cognitive abilities of the patient;

- an input unit connected to said computer for use by said patient during said interactive procedure for acquiring said information;

- an expert system accessible by said computer able to receive said information and produce a quantified indicator from said information and making said quantified indicator available to said computer; and

- an output unit connected to said computer for providing said quantified indicator to the patient.

18. (Previously Presented) A system as claimed in claim 17 wherein said information is information characterizing a motor function of the patient, and wherein said input unit is a manually operated input unit, and wherein said software program operates said computer to execute motor function test exercises and produces a

quantified information value quantifying at least one of neutral, negative and positive effects of said medication on said motor function and makes said quantified information value available to said expert system.

19. (Original) A system as claimed in claim 17 wherein said information is information characterizing verbal communication abilities of the patient, and wherein said input unit is an acoustical input unit, and wherein said software program assesses speech made by said patient into said input unit using speech algorithms and a phonetic data bank, and produces a quantified information value representing said verbal communication abilities, and makes said quantified information value available to said expert system.

20. (Previously Presented) A system as claimed in claim 17 wherein said information is information characterizing cognitive abilities of the patient and wherein said software operates said computer to present questions to said patient and to receive responses from said patient, and produces a quantified information value from said responses quantifying at least one of neutral, negative and positive effects of said medication on said cognitive abilities, and makes said quantified information value available to said expert system.

21. (Original) A system as claimed in claim 17 comprising a further software program for operating said computer to obtain additional information from said patient characterizing a subjective state of health of said patient.

22. (Original) A system as claimed in claim 17 wherein said software program in each interactive procedure produces a quantified information value from said information, and further comprising a memory accessible by said computer and by said expert system for storing, as stored information relative to time, at least one of said quantified indicator, said information and said quantified information value after each interactive procedure.

23. (Original) A system as claimed in claim 22 wherein said expert system produces an evaluation from said stored information with regard to a dosage of said medication.

24. (Original) A system as claimed in claim 23 wherein said stored information includes said quantified indicator, and wherein said expert system produces said evaluation by analyzing a chronological curve of respective quantified indicators obtained from successive interactive procedures.

25. (Original) A system as claimed in claim 24 wherein said computer provides said chronological curve to said output device as a displayed curve.

26. (Original) A system as claimed in claim 23 further comprising a transmission link from said computer to an external computer located remotely from said computer for transmitting at least one of said evaluation and said quantified indicator to said external computer.

27. (Original) A system as claimed in claim 17 wherein said software operates said computer to formulate said quantified indicator as a number.

28. (Original) A system as claimed in claim 17 wherein said software operates said computer to formulate said quantified indicator as a statement.

**APPENDIX II - EVIDENCE**

Applicant does not rely on any additional evidence other than the arguments submitted hereinabove.



**APPENDIX III - RELATED PROCEEDINGS**

Applicant respectfully submits that there are no proceedings related to this appeal in which any decisions were rendered.

**APPENDIX IV - TABLE OF CASES**

1. *In re Howard*, 394 F. 2d 869, 157 USPQ 615, 616 (CCPA 1968)
2. 29 AM. Jur 2D Evidence S. 33 (1994)  
*In re Ahlert*, 424 F. 2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970)
3. *In re Eynde*, 480 F. 2d 1364, 1370; 178 USPQ 470, 474 (CCPA 1973)
4. *In re Fine*, 5 USPQ 2d 1600, (Fed Cir. 1988)
5. *ACS Hospital Systems Inc v. Montefiore Hospital*, 221 USPQ 929,933  
(Fed. Cir. 1984)0
6. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (CCPA 1966)
7. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438  
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**APPENDIX V - LIST OF REFERENCES**

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